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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,497	11/21/2001	Robert Waranis	RPS6096-US	3407
43971	7590	02/23/2005	EXAMINER	
CARDINAL HEALTH 7000 CARDINAL PLACE LEGAL DEPARTMENT - INTELLECTUAL PROPERTY DUBLIN, OH 43017			HOWARD, SHARON LEE	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,497

Applicant(s)

WARANIS ET AL.

Examiner

Sharon L. Howard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/14/04, 9/21/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9 and 11-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-9 and 11-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
AK1615

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

The examiner acknowledges receipt of the remarks, the one-month extension of time and the request for continued examination (RCE) filed on 9/21/04.

Claims 1,7,9 are currently amended.

Claims 2 and 10 have been cancelled.

DETAILED ACTION

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3,6,9,11,14 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu etl. (U.S. 50271643) in view of Honour et al. (U.S. 5529923) in further view of Veech (U.S. 6020007).

Yu teaches a pharmaceutical carrier system (i.e. a solvent system) for acetaminophen comprising acetaminophen (col.5, lines 13-17), polyethylene glycol (col.4, line 41 – col.5, line 7, col.6, lines 23-35), including hydroxide ions, water, glycerin and polyvinyl pyrrolidone (col.7,

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lines 10-12). Yu teaches that the solvent system and solution are suitable for soft gel encapsulation (see col.9, lines 18-24, col.10, lines 39-49).

Yu does not particularly teach the inclusion of a lactate salt.

However, Honour teaches sodium lactate, which is an additive known in a solution composition (see col.8, lines 56-64).

Veech is relied upon for the teaching of l-lactate salt. Veech teaches that the l-form of the salt is preferred in physiological conditions (see col.2, lines 52-62)>

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the solvent system of the Yu reference to include a lactate salt taught by Honour, having the reasonable expectation of achieving a composition comprising acetaminophen and a l-lactate salt which is known in the art to be suitable for softgel encapsulation.

Claims 4,5,7,8,12,13,15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al. '643 in view of Honour et al. '923 and in further view of Veech '007 and Shelley et al. (U.S. Patent No. 5505961).

The teaching of Yu, Honour and Veech are discussed above, but do not teach the inclusion of potassium acetate.

However, Shelley teaches a clear solvent system similar to Yu's system but comprising potassium acetate (see col.3, lines 21-27). Shelly teaches that the potassium acetate aids in the solubility of acetaminophen.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the solvent system of the Yu and Honour references to include potassium

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acetate, having the reasonable expectation of obtaining a softgel gelating capsule containing acetaminophen, polyethylene glycol, polyvinyl pyrrolidone and sodium l-lactate and one would expect to achieve similar beneficial results.

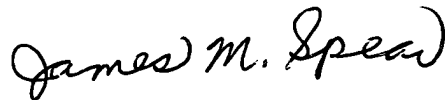
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sharon Howard
February 22, 2005



JAMES M. SPEAR
PRIMARY EXAMINER

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